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EXAMINER	
STEELE, JENNIFER A	

ART UNIT	PAPER NUMBER
1794	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/802,395	KREIDLER ET AL.	
	Examiner	Art Unit	
	JENNIFER STEELE	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42,54-68,74 and 81* is/are pending in the application.

4a) Of the above claim(s) *42,62 and 64-67* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-41, 54-61, 63, 68 and 74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/24/2009 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claim 1-41, 54-61, 63, 68, 74 and 81 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1, 36, 54 and 61 are amended to include the limitation "the first and second membrane layer are configured to permit tissue ingrowth through the first and second membrane layers". The specification paragraph [0035] describes "The composite membrane has a composite membrane open surface area in the range between about 10% and about

50%, and the composite membrane open surface area permits tissue ingrowth through the composite membrane and across at least one of the first and second membranes". The specification does not teach "tissue ingrowth through the first and second membrane layers", the specification teaches "tissue ingrowth through the composite".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. **Claim 1-4 and 21-22 rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Melican et al (US 2002/0120348).** Melican teaches a biocompatible tissue implant. The implant comprises one or more layers of a bioabsorbable polymeric foam having pores with an open cell structure (ABST). The tissue implant also includes a reinforcement component wherein the reinforcement component is mesh and is bonded to the porous foam layers by the foam which penetrates the mesh to interlock the layers together [0010].

Applicant claims a porous first membrane layer and a porous second membrane layer. Applicant describes the membrane layers as barrier layers produced from a

variety of materials which facilitate cellular ingrowth such as expandable PTFE, Applicant's specification [0085]. Expandable PTFE is equated with Melican expandable polymer layer called a foam layer. As the polymeric foam layers of Melican also facilitate tissue ingrowth, the polymeric foam layers of Melican are equated with the porous membrane layers of the current Application.

Melican also teaches barrier layers that enable certain surface properties of the structure such as porosity, permeablity, degradation rate and mechanical properties [0060].

Melican teaches a preferred tissue ingrowth promoting structure is one where the cells of the foam component are open and sufficiently sized to permit cell ingrowth [0023]. Therefore, Melican teaches a structure wherein the layers are configured to permit tissue ingrowth through the first and second membrane layers and across the surface of at least one of the first and second membrane layers.

The structure of Melican is shown in Fig. 1 and Fig. 3 where the layers 12 are the porous polymer foam layers and 14 is a reinforcement mesh (shown in Fig. 6). Layer 16 is an additional barrier layer that can be on one or both sides of the laminate. (Note: figures are taken from the US Patent document 6,599,323 because the PGPub. drawings were hand drawn).

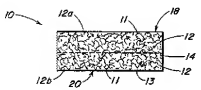

FIG. 1

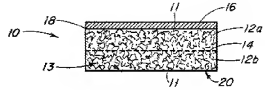

FIG. 3

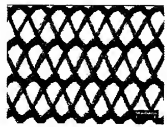

FIG. 6

As to claims 2-4, Melican teaches the reinforcement layer is inbetween the first and second membrane layers. Melican has sufficient porosity to facilitate cellular ingrowth and attachment.

As to claim 21-22, Melican teaches the bonding or reinforcement layer has an "openness" or density of the mesh is 12-80%. The openness of Melican is equated with open surface area of the current application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

> the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. **Claim 5-19, 20, 23-29, 32-33, 36-41, 55-56 and 60-61 rejected under 35 U.S.C. 103(a) as being unpatentable over Melican et al (US 2002/0120348) in view of Shaw et al (US 5,879,366) and Notaras et al (WO 9603091).** As to claims 5-17, Melican differs and does not teach the thickness of the layers.

Shaw teaches a self expanding device for sealing a defect tissue or muscle (col. 1, lines 6-15). Shaw teaches a structure of thin membranes laminated together with an embedded super-elastic wire (col. 2, lines 37-47). Shaw teaches the membranes are of ePTFE cross-laminated to increase membrane strength. Shaw teaches the membranes are porous ePTFE (claim 65).

Shaw teaches the membranes are each approximately 0.0025 mm to 0.025 mm thick which is equal to 0.0001 to 0.001 inches. Shaw teaches laminates of 2, 4, 6, 8 and 10 plies, and Shaw teaches a total laminate thickness of 0.0002 to 0.002 which overlaps the range of the claimed invention. Shaw presents a finding to one of ordinary skill in the art that a biocompatible membrane with layer thicknesses in the range 0.001 to 0.010 inches and less than 0.005 and 0.003 and 0.002 could be employed with a

reasonable expectation of success. As Shaw teaches the individual layer thicknesses of the ePTFE film in the range of 0.0002 to 0.002 inches and teaches that a range of plies can be employed, Shaw teaches a laminate that could be no more that 2 or 3 times the first or second membrane layer thicknesses.

Notaras teaches a surgical mesh of substantially uniform thickness that is useful for hernia repair and abdominal wall reinforcement (page 1, lines 1-5). Notaras teaches the mesh thickness is from 0.05 to 2 mm thick which is 0.0019 inches to 0.078 inches thick.

It would have been obvious to one of ordinary skill in the art to substitute the membranes of Shaw and the structural mesh of Notaras in the structure of Melican motivated to produce a thin laminate for tissue repair with the desired overall and individual layer thickness. As Shaw and Notaras teach that it is known in the art to produce a membrane laminates and mesh of thicknesses in the range of the claimed invention, one of ordinary skill in the art could have combined the known features with a reasonable expectation of success.

As to claim 20, Melican teaches the bonding or reinforcement layer has an "openness" or density of the mesh is 12-80% but differs and does not teach the average spacing between adjacent pores. Notaras teaches the pore size is from 0.5 to 10 mm which is equivalent to 0.019 inches to 0.39 inches and in the claimed range.

As to claims 23-25, Melican differs and does not teach the softening or melting point of the bonding or reinforcement layer. Notaras teaches a surgical mesh comprised of nylon, polypropylene, polyester or carbon fiber. Polypropylene which

would have a melting point of 177°C (350°F) and has a Vicat softening point of 138-150°C (280-311°F).

As to claims 26-27, Melican differs and does not teach the thickness of the foam layers. Shaw teaches the individual layer thicknesses of the ePTFE film is approximately 0.0025 mm to 0.025 mm thick which is equal to 0.0001 to 0.001 inches in the claimed range of claims 26 and 27.

As to claims 28 and 29, Melican teaches the openness of the bonding (mesh layer) and Melican teaches the foam or membrane layers have suitable pore size with an average diameter in the range of 100-1000 microns and about 150-500 microns. Melican teaches the porosity is desired to achieve tissue ingrowth [0023]. Melican does not teach the open surface area of the first membrane layer. It would have been obvious to one of ordinary skill in the art to optimize the membrane layer porosity motivated to achieve the desired porosity for adequate tissue ingrowth.

As to claims 30-31, Melican differs and does not teach the melting points of the first membrane layer. Melican teaches biocompatible polymers used to produce the foam membranes can be polymers such as aliphatic polyesters as well as polyether-esters. Aliphatic polyesters have glass transition temperatures of 125°C which is equivalent to 257°F. A glass transition temperature is an equivalent measure of softening point. Evidence of the polyester properties if found in the Encyclopedia of Polymer Science and Technology article "Polyesters" by Reese.

As to claims 32-33, Melican differs and does not teach the melting points of the first membrane layer. Melican teaches biocompatible polymers used to produce the

foam membranes can be polymers such as aliphatic polyesters as well as polyether-esters. Aliphatic polyesters have melting points of 146°C which is equivalent to 296°F.

As to claims 34 and 35, Melican differs and does not teach a difference between the softening point of at least one of the first and second membranes and the bonding layer. As the combination of Melican and Notaras teach softening points of the membrane of 257°F and softening points of the mesh of 280-311°F the difference would be in the claimed range of about 25°F to 50°F about 200°F to 100°F.

As to claim 36-41, Melican does not teach a support structure. Shaw teaches a biocompatible laminate fabric embedded with a wire support structure (ABST) that allows the membrane to be collapsed and then expanded when in place to repair the damaged tissue or organ where a small hole needs to be sealed (ABST). It would have been obvious to employ the laminate of Melican in combination with a support structure motivated to enable one to place the tissue repair laminate in the desired location within the body.

As to claim 55, Melican differs and does not teach the membrane layers are ePTFE. Shaw teaches the membrane layers are ePTFE. It would have been obvious to substitute the ePTFE of Shaw in the laminate of Melican motivated to produce a laminate for tissue repair.

As to claim 56, Melican differs and does not teach the thickness of the membrane layers. Shaw teaches the membranes are each approximately 0.0025 mm to 0.025 mm thick which is equal to 0.0001 to 0.001 inches.

As to claim 60, Melican differs and does not teach the thickness of the layers.

Shaw teaches the membranes are each approximately 0.0025 mm to 0.025 mm thick which is equal to 0.0001 to 0.001 inches. Shaw teaches laminates of 2, 4, 6, 8 and 10 plies, and Shaw teaches a total laminate thickness of 0.0002 to 0.002 which overlaps the range of the claimed invention. Shaw presents a finding to one of ordinary skill in the art that a biocompatible membrane with layer thicknesses in the range 0.001 to 0.010 inches and less than 0.005 and 0.003 and 0.002 could be employed with a reasonable expectation of success.

As to claim 61, Melican teaches the features of claim 61 as noted above however Melican does not teach a frame. Shaw teaches the laminate has a wire structure that embedded in the laminate. The wire structure is equated with a frame as claimed.

3. **Claim 54, 57-59 rejected under 35 U.S.C. 103(a) as being unpatentable over Melican et al (US 2002/0120348).** As to claims 54, Melican teaches the openness of the bonding (mesh layer) and Melican teaches the foam or membrane layers have suitable pore size with an average diameter in the range of 100-1000 microns and about 150-500 microns. Melican differs and does not teach an open surface area in the range between about 10% to 50%. As Melican teaches the pore size is desired to allow adequate tissue ingrowth [0023] and Melican teaches barrier layers can also be employed to aid or retard the tissue ingrowth and diffusion of nutrients while limiting the migration of cells into the implant and the barrier layer also assists in the prevention of postsurgical adhesions. As Melican teaches the laminate has the same structure as the claimed invention and teaches a pores size of the membrane layer and the reinforcing

mesh layer and Melican teaches the laminate provides tissue ingrowth, one of ordinary skill in the art could have optimized the laminate of Melican to produce a membrane with an open surface area as claimed.

As to claims 57 and 58, Melican teaches the pore diameter of the membrane layer can be 100-1000 microns. Melican does not teach an internodal distance. As Melican teaches a laminate with a pore size structure to permit the ingrowth of tissue it is presumed that the structure of Melican would have the claimed internodal distance between the pores or could be optimized to achieve the desired internodal distance.

As to claim 59, Melican teaches the biocompatible polymer can be a polyethylene [0050].

4. **Claim 63, 68, 74 and 81 rejected under 35 U.S.C. 103(a) as being unpatentable over Melican et al (US 2002/0120348) in view of Colone et al (US 6,443,981).** As to claim 68, Melican does not teach the frame comprises a stent and does not teach the stent has a first end diameter that is smaller then the cylindrical body length as recited in amended claim 74.

Colone teaches an expandable vascular prothesis comprising a wire stent. Colone teaches interior and exterior layers of ePTFE. The stent is cylindrical. The interior layer and the exterior layers of ePTFE have a first end diameter that is smaller than the cylindrical body length. The stent shown in Fig. 5 shows the length is 50". The tubes may have diameters **D** of up to 22 mm with a wall thickness of 0.006" (col. 5, lines

55-60). Therefore Colone teaches the limitation that the end diameter is smaller than the cylindrical body length. Fig. 5 of Colone is shown below.

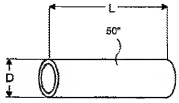

FIG. 5

It would have been obvious to employ the laminate of Melican as the ePTFE interior and exterior layers of the stent of Colone that has the geometric limitations as claimed.

As to claim 81, Melican teaches the laminate has a pore size that is configured to permit tissue ingrowth across the laminate layers.

5. **Claim 1-4, 20, 23-39 and 54-61 rejected under 35 U.S.C. 103(a) as being unpatentable over Eldridge et al (US 6,120,539) in view of Shaw et al (US 5,879,366) and in further view of Zukowski (US 5,462,781).**

Eldridge teaches a prothetic repair fabric comprised of a sheet of tissue infiltratable fabric and a second sheet of tissue infiltratable fabric which is fused to an adhesion resistant barrier forming a laminate composite prosthesis without degrading the mechanical properties or tissue ingrowth capability of the first sheet (ABST). Eldridge teaches that prior art prosthetic repair materials have raised the concern that mesh may form postoperative adhesions with abdominal viscera and to alleviate these concerns it had been proposed to cover the MARLEX mesh with an adhesion resistant

barrier such as a sheet of ePTFE (col. 1, lines 16-27). Eldridge teaches the tissue infiltratable fabric is a mesh fabric such as a MARLEX mesh and the adhesion resistant barrier is layer of ePTFE (col. 1, lines 31-38 and col. 4, lines 6-21). Eldridge teaches a process for adhering the ePTFE barrier to the mesh wherein the mesh becomes encapsulated in the submicron porous network of the expanded PTFE sheet. The adhesion resistant barrier layer of ePTFE of Eldridge is equated with the porous first membrane layer. The MARLEX mesh of Eldridge is equated with the open mesh bonding layer.

Eldridge differs from the current invention and does not teach a second porous membrane layer.

Eldridge teaches a laminate that has the properties of tissue ingrowth, however the tissue ingrowth is within the mesh fabric layers. **Eldridge differs and does not teach the barrier membrane allows for tissue infiltration and therefore does not teach the limitation wherein the composite member is configured to permit tissue ingrowth through the first and second membrane layers.**

Shaw teaches a self expanding device for sealing a defect tissue or muscle (col. 1, lines 6-15). Shaw teaches a structure of thin membranes laminated together with an embedded super-elastic wire (col. 2, lines 37-47). Shaw teaches the membranes are of ePTFE cross-laminated to increase membrane strength. Shaw teaches the membranes are porous ePTFE (claim 65).

Zulowski teaches a surface modified porous expanded polytetrafluoroethylene and method for making (Title). Zulowski teaches the porous expanded PTFE has node

interconnected by fibrils (ABST). The porous expanded PTFE is for use in implantable applications (col. 5, lines 48-55). Zulowski teaches for applications involving contact with soft tissues where tissue ingrowth into the void spaces is desirable, the rate or quality of tissue ingrowth may be improved by the use of a porous expanded PTFE having a surface of freestanding nodes from which the fibrils have been removed (col. 5 and 6, lines 62-67 and 1-13).

It would have been obvious to combine the features of the structure of Shaw that has multiple ePTFE membranes with a wire support with structure of Eldridge that teaches a support mesh with a single ePTFE membrane motivated to produce a biocompatible laminate for use in tissue repair that has the desired properties of porosity and resistance to tissue adhesion. It further would have been obvious to employ a membrane, such as the ePTFE taught by Zulowski, motivated to produce a laminate with the properties of good tissue ingrowth.

Regarding claim 2 and 37, Eldridge teaches a mesh support structure with only one membrane layer. Shaw teaches multiple membrane layers with an embedded wire support structure. It would have been obvious to combine the features of multiple membrane layers of Shaw with the mesh laminated membrane structure of Eldridge and the results of the combination would have been predictable. This is merely the duplication of parts which provide the same function.

With regards to claim 3, 4, 38 and 39, Eldridge teaches the laminate is porous and is intended for tissue growth and attachment and Eldridge teaches physical and performance characteristics were tested such as pore size, surface roughness, suture

retention strength and burst strength (col. 5, lines 14-19). Eldridge teaches In-Vivo testing for tissue ingrowth (col. 6, lines 10-40).

As to claim 20, Eldridge teaches an average spacing between the mesh pores of 0.125 inches (col. 3, lines 47).

Regarding claim 23-25, Eldridge teaches a monofilament polypropylene which would have a melting point of 177°C (350°F). Eldridge teaches a process where the laminate is heated to a temperature of 350-400°F which is equal to 176 to 204°C. Applicant teaches a process where the laminate is heated to a temperature that is greater than the softening temperature of the bonding layer and less that the membranes and that temperature is in the range of 100 to 300 degree Celsius [0102]. The bonding layer softening point of Eldridge is equated with the bonding layer softening point of the current application.

As to claims 26, Eldridge teaches an ePTFE layer of thickness 0.0035 inches which is in the range of claim 26.

As to claim 27, Eldridge differs and does not teach an ePTFE membrane layer thickness of 0.001 to 0.002 inches. Shaw teaches ePTFE membranes that can have a thicknesses in the range of approximately 0.0025 mm to 0.025 mm thick which is equal to 0.0001 to 0.001 inches and in the range of the membrane thicknesses that are claim 27.

Regarding claim 28 and 29, Eldridge differs and does not teach the property of open surface area of the membrane. Eldridge teaches the ePTFE membranes have a surface pore size of 0.74 +/- 0.3 microns (Table 1, col. 6). As Eldridge is teaches a

membrane biocompatible laminate comprised of ePTFE which is the same materials and structure as the claimed invention, it is presumed that the property of surface area would be inherent to the structure of the claimed invention.

As to claims 30-35, Eldridge teaches the same membrane material as the Applicant, the property of softening point is presumed to be the same as the Applicants. Eldridge further teaches that the bonding layer or knit mesh melts and becomes encapsulated in the porous network of the PTFE sheet and therefore teaches that the bonding layer is of a lower melting temperature than the membrane.

Regarding claims 36-39, Eldridge laminate material is implantable and therefore, the above rejection of Eldridge in view of Shaw meets the new limitation of an implantable medical device comprising a biocompatible laminate.

As to claims 54-60, Eldridge in view of Shaw teaches a laminate membrane for use as a medical device comprising a first membrane a bonding mesh layer and a second membrane as noted above. Eldridge in view of Shaw differ from the current application and does not teach the property of open surface area in the range between about 10-50%. However as the laminate of Eldridge in view of Shaw teaches the structure and materials of the claimed in invention, it is presumed that the property of open surface area would be inherent in this structure.

As to claim 55, Eldridge teaches an ePTFE membrane.

As to claim 56 , Eldridge teaches a membrane of a thickness of 0.0035 inches.

As to claim 57, Eldridge teaches a pore size of 0.74 +/- 0.3 micron which could be 1.04 micron and therefore encompasses the claimed range about 1 micron to about 200 micron.

As to claim 58, Eldridge differs and does not disclose the internodal distance in the membrane. Zulowski teaches an ePTFE membrane that has nodes to allow for void spaces for tissue ingrowth. Zulowski differs and does not teach the internodal spacing. However as Zulowski teaches the claimed structure and materials with the same property of tissue ingrowth as well as a method for producing the nodes, one of ordinary skill in the would have been able to optimize the structure of Zulowski motivated to produce the desire feature of tissue ingrowth.

As to claim 59, Eldridge teaches a mesh bonding layer comprised of polypropylene and differs and does not teach a polyethylene mesh bonding layer. Shaw teaches membrane layers that can be manufactured of polyester, polyethylene, polypropylene, fluoropolymers, polyurethane foamed films, silicone, nylon, silk, thin sheets of super-elastic materials, woven materials or any other biocompatible materials (col. 4, lines 58-68). It would have been obvious to substitute polyethylene for polypropylene in the bonding layer mesh.

As to claim 60, Eldridge teaches a laminate of a thickness of 0.0635 inches which is in the range of claim 60.

Regarding claims 61 that are drawn to a medical device comprising a frame Eldridge differs from the current application and does not teach a frame or a laminate for a stent. Shaw teaches a composite laminate that is configured with an elastic wire

frame structure so that the device can be collapsed and then expanded. Shaw teaches a star shaped wire frame for a defect closure device as shown in Fig. 1 (col. 5, lines 28-40).

6. **Claim 63, 68, 74 and 81 rejected under 35 U.S.C. 103(a) as being unpatentable over Eldridge et al (US 6,120,539) in view of Shaw et al (US 5,879,366) and Zukowski (US 5,462,781) in further view of Colone et al (US 6,443,981).**

As to claim 63, 68, **74** and 81, Eldridge in view of Shaw differ do not teach the frame comprises a stent and does not teach the stent has a first end diameter that is smaller then the cylindrical body length as recited in amended claim **74**.

Colone teaches an expandable vascular prothesis comprising a wire stent. Colone teaches interior and exterior layers of ePTFE. The stent is cylindrical. The interior layer and the exterior layers of ePTFE have a first end diameter that is smaller than the cylindrical body length. The stent shown in Fig. 5 shows the length is 50". The tubes may have diameters **D** of up to 22 mm with a wall thickness of 0.006" (col. 5, lines 55-60). Therefore Colone teaches the limitation that the end diameter is smaller than the cylindrical body length. Fig. 5 of Colone is shown below.

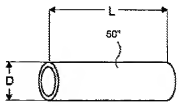

FIG. 5

It would have been obvious to combine the features of a laminate of Eldridge and Shaw with the structure of the stent of Colone that has the geometric limitations as claimed motivated to produce a tissue repairing stent.

As to claim 81, Eldridge in view of Shaw and Zulowski teach the laminate has a pore size that is configured to permit tissue ingrowth across the laminate layers.

7. **Claim 5-19, 21, 22, and 40-41 rejected under 35 U.S.C. 103(a) as being unpatentable over Eldridge et al (US 6,120,539) in view of Shaw et al (US 5,879,366) and Zukowski (US 5,462,781) and in further view of Notaras et al (WO 9603091).**

As to claims 5-9, and 40-41, Eldridge teaches a laminate wherein the mesh fabric has a thickness of 0.06 inches and a membrane with a 0.0035 inch thickness and an overall thickness of 0.0635 inches. The thickness of Eldridge is greater than the claimed invention because the mesh is thicker than the claimed invention.

Shaw teaches the membranes are each approximately 0.0025 mm to 0.025 mm thick which is equal to 0.0001 to 0.001 inches. While Shaw laminates of 2,4,6, 8 and 10 plies, Shaw teaches a total laminate thickness between 0.0002 to 0.002 which overlaps the range of the claimed invention. Shaw presents a finding to one of ordinary skill in the art that a biocompatible membrane with layer thicknesses in the range 0.001 to 0.010 inches and less than 0.005 and 0.003 and 0.002 could be employed with a reasonable expectation of success. As Shaw teaches the individual layer thicknesses of the ePTFE film in the range of 0.0002 to 0.002 inches and teaches that a range of plies

can be employed, Shaw teaches a laminate that could be no more that 2 or 3 times the first or second membrane layer thicknesses.

Notaras teaches a surgical mesh of substantially uniform thickness that is useful for hernia repair and abdominal wall reinforcement (page 1, lines 1-5). Notaras teaches the mesh thickness is from 0.05 to 2 mm thick which is 0.0019 inches to 0.078 inches thick.

It would have been obvious to one of ordinary skill in the art to employ a membrane laminate with an overall thickness as taught by Shaw employing a structural mesh of thickness as taught by Notaras motivated to produce a thin laminate for tissue repair. As Shaw and Notaras teach that it is known in the art to produce a membrane laminate and mesh of thicknesses in the range of the claimed invention, one of ordinary skill in the art could have combined the elements with a reasonable expectation of success.

Regarding claims 14-17, Eldridge in view of Shaw differ and do not teach a mesh bonding layer with an average thickness of 0.0005 to 0.005 inches. Notaras teaches a surgical mesh with a thickness of 0.0019 to 0.078 inches which is in the claimed ranges of 0.0008 to 0.004 inches and 0.0009 to 0.003 inches and 0.001 to 0.002 inches. It would have been obvious to one of ordinary skill in the art to employ the mesh of Notaras motivated to produce a surgical laminate of the desired thickness.

With respect to claims 18-19, Eldridge teaches a mesh bonding layer that has a knit structure with a predetermined spacing pattern (col. 3, lines 42-50) but differs and does not teach the average pore cross-section. Notaras teaches a surgical mesh with a

pore size that may be determined according to the use of the mesh for a particular operation. Notaras teaches it may be above 100 micron such as 0.5 to 10 mm, preferably 1.5 to 4 mm (page 4, lines 26-36). Notaras teaches a mesh that is 0.019 inches to 0.39 inches, preferably 0.06 inches to 0.16 inches. It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a mesh with a pore size as taught by Notaras motivated to produce the desired properties of strength, porosity and adhesion in the laminate.

As to claims 21 and 22, Eldridge in view of Shaw and Notaras differ and do not teach the feature of open surface area of the bonding layer. Eldridge teaches the spacing between the pores can be 0.125 inches and in the range of the claimed invention. Notaras teaches a mesh with an average pore size in the range of the claimed invention and teaches the pore sized may be determined according to the use for the particular operation. However as Eldridge and Notaras teach the structure and materials of the claimed invention, it is presumed that the feature of open surface area would be inherent to the meshes of prior art and therefore it would have been obvious to employ a bonding mesh with an average open surface area of 10-90% and 30- 60% motivated to produce the desired properties of strength, porosity and adhesion.

Response to Arguments

8. Applicants amended the independent claims to include the limitation that "the first and second membrane layers are configured to permit tissue ingrowth through the first

and second membrane layers". The newly recited limitation has been rejected under 35 USC 112 1st paragraph as new subject matter.

9. Applicant's amendments and arguments with respect to claims 1-42, 54-68, 74 and 81 have been considered but are moot in view of the new ground(s) of rejection. Applicant argues that Eldridge does not teach a laminate with a membrane layer that promotes tissue ingrowth. While Eldridge does teach a laminate that promotes tissue ingrowth, the barrier membrane layer does not as is stated by Eldridge: "The barrier sheet may be formed of ePTFE having a fine pore size that discourages tissue ingrowth and viscera adhesion". A new grounds of rejection is presented to respond to the new limitation with reference to Zulowski which teaches that barrier membranes of ePTFE can be constructed to have the desired porosity to promote tissue ingrowth.

10. Applicant argues that Shaw fails to teach tissue ingrowth and Examiner agrees that Shaw does not teach this property. However, Shaw does not teach that the ePTFE membranes do not allow tissue ingrowth and it is reasonable to presume that Shaw's invention promotes tissue ingrowth. For clarity, the present Office Action presents anew reference to Zulowski for teaching this feature.

11. Applicant's arguments with respect to amended claim 74 are persuasive in that Shaw fails to teach the stent as claimed. A new 35 USC 103 rejection with reference to Colone which teaches the claimed stent features is presented in this Office Action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER STEELE whose telephone number is (571)272-7115. The examiner can normally be reached on Office Hours Mon-Fri 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye can be reached on (571) 272-3186. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. S./
Examiner, Art Unit 1794

/Elizabeth M. Cole/
Primary Examiner, Art Unit 1794

9/21/2009